AMERICAN SOCIETY FOR MICROBIOLOGY

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Presented by

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Mr. Chairman, members of the Subcommittee, my name is Ronald Atlas and I am pleased to present testimony on behalf of the American Society for Microbiology (ASM) concerning research and development activities of the Department of Homeland Security (DHS). I am Graduate Dean at the University of Louisville, where I also co-chair the Center for Health Hazards Preparedness. I also co-chair the Committee on Biodefense of the ASM Public and Scientific Affairs Board. The ASM is the largest single life science society with more than 42,000 members, and its principal goal is the study and advancement of scientific knowledge of microbiology for the benefit of human welfare. ASM members are involved in research, clinical, and public health efforts, focused on developing new preventions, therapies, and cures for infectious diseases.

The ASM supports and encourages the efforts by the DHS Science and Technology (S&T) Directorate to provide effective programs that protect our nation against bioterrorist threats. Science and technology play a critical role in homeland security whether disasters are caused by terrorist or natural events. DHS has made significant strides to improve cutting-edge technology and systems that enhance emergency response capabilities. We believe, however, that the nation's scientific community can and should be better engaged by DHS in this effort to ensure that the best approaches are developed and employed to protect against the potentially catastrophic effects of bioterrorism. In this regard, the ASM strongly supports the recommendations of the National Academy of Sciences (NAS) to increase the involvement and guidance of the broader scientific community with the DHS. The need for greater scientific input is particularly important because of DHS's role in making risk assessments about biothreats that identify countermeasure needs not only for the R&D programs of DHS S&T but also for the public health programs at other agencies, including the Department of Health and Human Services (HHS).

It is important that the DHS S&T Directorate build public confidence in its activities, that they be effectively coordinated with other federal agencies with a biodefense focus, and that they be based on sound science policy. In our view, it is especially important for the DHS S&T Directorate to have clear and robust peer review processes to ensure the merit and high quality of its biodefense-related research programs. We urge Congress to reauthorize the charter for the Homeland Security Science and Technology Advisory Committee (HSSTAC) and also for the DHS to establish appropriate external advisory panels. Our testimony will also focus on the need to improve threat assessment and other DHS assigned activities through greater engagement with the scientific community, including greater involvement of peer review; the need for funding for the DHS university based Centers of Excellence, fellowships and training programs to encourage students to pursue areas of study related to homeland security; the need for more R&D on environmental detectors; the continuation of efforts to improve the BioWatch system of environmental surveillance; and the need for a centralized animal health organization.

DHS Should Develop a Strategic Plan and Seek Scientific Input to Set Priorities for Funding

The terrorist events of September 11, 2001, and the subsequent anthrax attacks led to a substantial restructuring of government agencies to defend against terrorist attacks. Part of that change was aimed at bringing forth the best efforts of the scientific, medical, public health, and engineering communities to meet these national needs. In June 2002, the Administration proposed to establish the Department of Homeland Security (DHS), and the Congress quickly mandated the DHS through the Homeland Security Act of 2002. This Act provides for an Undersecretary for Science and Technology to oversee DHS research activities aimed at developing countermeasures for acts of terrorism, including bioterrorism.

To refine the specific responsibilities of the DHS in defending against bioterrorism, the Administration issued Homeland Security Presidential Directive 10 (HSPD-10), *Biodefense for the 21st Century*. According to that Directive, "The Department of Homeland Security, in coordination with other appropriate federal departments and agencies, is developing comprehensive plans that provide for seamless, coordinated federal, state, local, and international responses to a biological attack." The ASM believes that HSPD-10 establishes an appropriate division of responsibilities in the area of biodefense and that DHS has an appropriate lead role in formulating coordinated plans.

The ASM believes that development of those plans requires critical inputs from the scientific community. The ASM also agrees with the House and Senate Homeland Security Appropriations Committee directives calling for the DHS to develop a strategic plan that delineates how it will coordinate with other federal agencies involved in biodefense. Importantly, the development of that plan requires critical input from the scientific community. The strategic plan also should be published in the Federal Register for review and comment.

The DHS Needs To Interact More Fully with the Scientific Community

Soon after the anthrax crimes in 2001, the National Academies of Science (NAS) undertook a comprehensive study which provided advice on protecting the nation against bioterrorism. The report, "Making the Nation Safer: The Role of Science and Technology in Countering Terrorism," includes chapters, that I and other members of the ASM, helped to write. It recommends a series of actions, including the development of new tools for the surveillance, detection, and diagnosis of bioterrorist threat agents; greatly expanded research programs aimed at increasing our knowledge of pathogenesis of and immune responses to biological agents; and research critical to deterrence, response, and recovery, particularly in areas involving decontamination and bioterrorism forensics.

Many recommendations in that report by the NAS were incorporated into the DHS R&D agenda. Moreover, the Congress assigned critical segments of those public health and research programs to the HHS. Thus, DHS plays a strategic role in defining the threat and

identifying needs for vaccines, therapeutics, diagnostics and detection and warning systems while the HHS maintains the major role in researching and stockpiling vaccines and therapeutic agents to protect the public against disease agents that could produce mass casualties through a bioterrorist attack.

The ASM strongly supports the HHS continuing to play this critical biodefense R&D function. Specifically, the ASM supports the lead role of the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID) in basic research and training and research resources, including an emphasis on translating basic research into the development of critical vaccines, diagnostics and therapeutics to combat infectious diseases and agents of bioterrorism.

Congress and the Administration appear to agree that major funding for biomedical research for biodefense should remain in the HHS. The ASM supports this approach because robust linkages between NIAID and the wider scientific community ensure that the best researchers are engaged in biodefense research. Moreover, the strong peer review system of the NIH further ensures the high quality of this research, and is suited to integrating basic biomedical research investigating emerging and re-emerging infectious diseases with other more applied research that will be needed to protect human health and national security against the threat of bioterrorism. By establishing Regional Centers of Excellence, NIAID is fostering efforts in both the academic and private sectors to develop defenses against a variety of infectious diseases—from anthrax to avian influenza. This capacity to derive dual benefits from research investments is proving critical for advancing human health and for meeting national security needs.

While supporting the paramount role of the NIH/NIAID in overseeing research to protect against infectious diseases and bioterrorism, the ASM also supports the strategic role of DHS in biodefense. That role includes prioritizing investments in biodefense-related research, development, planning, and preparedness. Biannual risk assessments should guide the setting of those priorities. However, the ASM is concerned that the DHS and the intelligence community are not adequately involving the broader science community in making threat assessments. This concern also was expressed in the NAS report, "Globalization, Biosecurity, and the Future of the Life Sciences," which calls for strengthening and enhancing the scientific and technical expertise within and across the security communities.

The ASM recommends stronger interactions among the DHS, intelligence, and scientific communities to develop a broad consensus on biothreats and to provide appropriate strategic guidance to the DHS S&T Directorate and the HHS Office of Public Health Emergency Preparedness. Such a consensus will also help to guide the Project BioShield countermeasure procurement process and the research agenda. The ASM and the broader scientific community stand ready to provide the guidance needed for developing medical countermeasures.

The DHS Centers of Excellence and Training Programs Need Sustained Support

The DHS has established six Centers of Excellence to create a university based capacity to engage the expertise of academia in addressing the science and education needs of the department. Ongoing merit review and evaluation of the work of these centers assures high quality performance and focus on the evolving needs of the DHS. Even in their formative phase, the value of the centers is being recognized as well as the need for eligibility for sustained support that will lead to dual benefits by meeting both national security as well as public health needs. The centers should be allowed sufficient time to demonstrate their contributions to the DHS S&T mission and at the local and state levels to enhance planning, prevention and emergency response. In this regard, we are concerned about the proposed provision in the Senate's version of the FY 2007 Homeland Security Appropriation bill that would preclude universities from re-competing for funding as a DHS Center of Excellence. In contrast, we believe that Congress should be seeking sustained excellence. We believe that the activities of these centers, as well as all other R&D activities of DHS S&T, can and should be assessed by continuing ongoing rigorous peer review to assure the public of their value.

The ASM considers fellowship and training programs an essential activity for DHS S&T to encourage students to pursue areas of study related to homeland security. While it is still too early to judge the outcomes of the fellowship support programs of DHS, it appears that they are attracting high quality students who can participate in the future protection and security of the nation. Like the Centers of Excellence, the ASM believes that these training programs need time to develop and should be supported and regularly assessed.

The ASM also believes it is important to build career tracks for those considering a career in DHS. As part of its training initiative, DHS should consider building a program modeled after the two-year epidemic intelligence service (EIS) program at CDC, begun soon after the inception of that agency. This program has led to a steady flow of bright young talented professionals in diverse fields, which have populated many of the leadership positions in CDC and in parallel state agencies in the following years. These EIS graduates have served the government in the field of public health with remarkable competency through the decades, and a similar program should be valuable for DHS.

Maintain NAS Committee that Advises the DHS and Strengthens Peer Review of DHS S&T programs

The ASM supports the role of the NAS Committee on Biodefense Analysis & Countermeasures, which was formed following a request from the DHS, in advising the department on technical issues and studies related to the DHS National Biodefense Analysis and Countermeasures Center (NBACC). The NBACC is managed by the DHS S&T Directorate and is part of the national interagency Homeland Security Biodefense Campus at Fort Detrick. NBACC programs provide knowledge of infectious properties of biological agents, effectiveness of countermeasures, decontamination procedures, and

forensics analyses to support policy makers and responders in developing policies, programs, and technologies. The technical advice from this committee should be viewed as critical for the NBACC to achieve its mandate in conducting biodefense R&D.

The ASM believes that the advice from the Committee on Biodefense Analysis & Countermeasures can help to allay concerns that have been raised about public oversight of the NBACC activities. In particular, this committee should help to address compliance issues regarding the Biological and Toxin Weapons Convention (BWC), which permits research only for defense against biological weapons. Oversight of such activities in federal facilities is very important for maintaining transparency and international confidence in the legitimacy of US biodefense programs.

Going beyond the role of the Committee on Biodefense Analysis & Countermeasures, the ASM recommends that the DHS and the NBACC have a formal peer review system—one that will have to balance secrecy requirements with the need for transparency to ensure the quality of research and development programs as well as and the legitimacy of the NBACC threat characterization efforts. Properly designed studies, formal advisory boards, and a robust system of peer review will reassure the Congress and the public of the value of the DHS S&T and NBACC investments. Coordinating the appropriate biodefense-related NBACC and HHS efforts is also important.

Congress Should Reauthorize the DHS Homeland Security Science & Technology Advisory Committee

The Homeland Security Act of 2002 directed the Secretary of the Department of Homeland Security to establish the Homeland Security Science and Technology Advisory Committee (HSSTAC). However, the DHS disbanded the HSSTAC as soon as the Congressional mandate for this committee expired. The ASM urges the Congress to reauthorize the HSSTAC charter. This committee, on which I served, brought together scientists, physicians, members of the business community, and first responders to provide the Undersecretary for S&T with broad advice and technical support.

The DHS and FBI Should Work Together on Microbial Forensics

The Administration designated NBACC the lead federal agency for forensic analysis of materials recovered following a biological attack. This is a new field of microbiology that requires coordination among scientists from several disciplines along with the law enforcement community. Separately, the FBI established a Scientific Working Group on Microbial Forensics to provide advice on the development of forensic methods and protocols, particularly those that can meet standards suitable within the US legal system. Although the DHS participates in those advisory meetings, it has not established a comparable advisory group. In the interest of addressing these important national biodefense needs, the ASM recommends that the DHS work more closely with this FBI Scientific Working Group and also consider establishing its own external microbial forensics advisory group.

BioWatch, Environmental Detection, and Decontamination Need Ongoing Assessments

Environmental detection is a critical activity for the DHS S&T. Early detection of infectious diseases—whether from natural outbreaks or bioterrorist attacks—is critical for curtailing morbidity and mortality. In terms of medical diagnoses, we rely on the medical and public health communities, giving a key role to the federal Centers for Disease Control and Prevention (CDC) for recognizing suspicious disease outbreaks.

For bioterrorism, however, early environmental detection can avert the catastrophic spread of disease or facilitate early treatments. The DHS S&T implemented the BioWatch system in several major cities to detect biothreat agents that can spread as aerosols. The DHS S&T Directorate funds the operational costs of the BioWatch system, which currently represent about a third of the S&T biological countermeasures budget. Because of the substantial cost of Biowatch within the S&T biological countermeasures budget, we must ensure that it does not divert funding from core research and development activities. Thus, we recommend that Congress and the Administration ensure the adequacy of the funding of S&T R&D activities to protect against future biological threats.

We further recommend that the DHS S&T Directorate focus on the research and development efforts needed to provide the nation with optimal environmental detectors. In particular, more research and development is needed to build a better system—one that could provide instantaneous accurate detection. Progress upgrading the current detection system and making it more cost-effective will help toward gaining the full confidence of the public health community. To meet the expectations of BioWatch the ASM recommends that this program, and the environmental detection systems it employs, be evaluated on a regular basis to determine their general effectiveness and reliability. As with other DHS S&T programs, the ASM believes that BioWatch should have a peer review system to ensure that it focuses on the most significant biothreat agents.

Although the Environmental Protection Agency is assigned the lead role, the DHS S&T should continue to play a critical role developing decontamination systems. Several DHS systems for environmental detection and decontamination are based on programs under way at several of the Department of Energy National Laboratories. Although seemingly innovative, these programs and the prototype detection systems that they are producing should be subject to rigorous peer review to ensure their quality. Lacking such review, the broader community may not develop confidence in these systems when a warning goes off or a facility is said to be decontaminated following a bioterrorism attack.

Finally, the Administration assigned major public communication responsibilities to the Department of Homeland Security. With other appropriate federal departments and agencies, the DHS is charged with developing comprehensive communication strategies in the event of a bioterrorism attack. However, the NAS study, “How Clean is Safe,” concluded that public acceptance of status reports is inevitably based on whether they trust what government officials tell them. Thus, communications from DHS need to be

credible if they are to be effective. The best methods for decontaminating facilities and the finest techniques for detecting bioterrorist outbreaks are of little use if the public does not believe in them.

Centralized Organization for Animal Health Issues Needed

Agriculture can be the target of bioterrorist attacks. The NAS report, "Making the Nation Safer," recommended establishing a centralized animal health surveillance organization equivalent to the CDC. It also recognized the need for increased R&D efforts to protect our food resources. The DHS S&T Directorate established two academic Centers of Excellence, one at Texas A&M University and the other at the University of Minnesota, for addressing agro-security issues. The DHS S&T Directorate also operates the Plum Island facility where infectious agents of agricultural importance are studied.

We need a first class facility where the most dangerous animal pathogens can be studied. Because the Plum Island facility needs significant upgrading, DHS is considering a number of alternate, more cost-effective, and more readily accessible sites for a facility. Constructing and operating an animal health facility on the mainland can be done safely; however, it may require the Congress to enact legislation permitting several animal pathogens, including those responsible for foot and mouth disease and rinderpest, to be studied on the US mainland. Such research is critical for the development of vaccines, therapeutic drugs, and detection methods to protect against diseases that could severely damage US agriculture and our economy. To foster the highest quality research it will be advantageous to have the facility interact with the NIH and DHS academic Centers of Excellence on key areas of research.

Conclusions

In conclusion, the ASM supports the critical roles given to DHS by HSPD-10 which make the DHS S&T programs of central importance for making the nation safer against threats of bioterrorism directed against humans and agriculture. We believe that HSPD-10 appropriately distributes shared responsibilities across the Federal government assigning to DHS a critical coordination role that is essential for defending the nation against a bioterrorist attack. The ASM strongly supports recommendations from the NAS to increase the involvement of the broader scientific community in assessing specific bioterrorist threats and, more generally, in guiding the efforts of both the DHS and the HHS in developing detection systems, medical countermeasures, decontamination methodologies, and other biodefense-related measures. Improved intelligence and threat characterization are also critical to these efforts.

The DHS S&T Directorate should reach out to the scientific community to help guide its efforts. Without such input, it will be difficult to build an effective public health response, one that the medical community and the public will trust. We think that the DHS should have robust peer review systems to guide its S&T efforts and to ensure the quality of its R&D efforts. We urge the Congress to reauthorize the charter for the HSSTAC and for the DHS to establish additional external advisory panels to guide its

R&D efforts. We recognize that the need for secrecy may conflict with the need for broadly based peer evaluations, but believe that these difficulties can be overcome. We strongly believe that DHS should provide enhanced support for agrosecurity since they are charged with this responsibility and the area is critically important to biodefense. The ASM stands ready to assist the DHS S&T directorate as well as all other agencies involved in defending our nation against bioterrorism.